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Attorney Docket No. 27234U

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

BETHKE et al.

Serial No.: 10/571,311

Group Art Unit: Not yet assigned

Filed: March 9, 2006

Examiner: Not yet assigned

For: **USE OF CICLESONIDE FOR THE TREATMENT OF RESPIRATORY DISEASES**

**TRANSMITTAL LETTER**

The Commissioner for Patents  
P. O. Box 1450  
Alexandria VA 22313-1450

Sir/Madam:

Submitted herewith for filing in the U.S. Patent and Trademark Office  
is the following:

- (1) Transmittal Letter;
- (2) Information Disclosure Statement;
- (3) PTO 1449 citing 36 references; and
- (4) Copies of 27 of the 36 references.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

Gary M. Nath  
Registration No. 26,965  
Sheldon M. McGee  
Registration No. 50,454  
Customer No. 34375

Date: June 12, 2006  
**NATH & ASSOCIATES PLLC**  
112 S. West Street  
Alexandria VA 22314  
Tel: (703) 548-6284

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. § 1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

- ☒ a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- ☐ b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311.
- The enclosed statement is accompanied by [check one]:
- ☐ i. a certification in part (e) below as specified in 37 C.F.R. § 1.97(e), or
- ☐ ii. a check in the amount required by 37 C.F.R. § 1.17(p).
- ☐ c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311, but before payment of the issue fee.
- ☐ Certification report(e) below; and
- ☐ a check in the amount as required by § 1.17(p).
- ☐ d. The enclosed statement is being filed pursuant to 37 C.F.R. § 1.97(i), for placement in the file.
- ☐ e. Certification [Check one] [Certification is required only if box (b) (i) or box (c) is checked.]

[ ] I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

[ ] I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

[ ] Appropriate certification is attached.

[ X ] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

[ X ] g. Copies of the documents are attached herewith with a completed Form PTO-1449.

And/or

[ ] h. Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

And/or

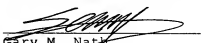
[ X ] i. Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

By:

  
Gary M. Nath  
Registration No. 26,965  
Sheldon M. McGee  
Registration No. 50,454  
Customer No. 34375

Date: June 12, 2006  
NATH & ASSOCIATES PLLC  
112 South West Street  
Alexandria, VA 22314  
Phone: 703-548-6284  
Fax: 703-683-8396



<b>FORM PTO-1449</b> <b>INFORMATION DISCLOSURE CITATION</b>	In re Application of: BETHKE et al.		Art Unit: Unknown
	Serial No: 10/571,311	Filed: March 9, 2006	Examiner: Unknown

**U.S. PATENT DOCUMENTS**

Examiner Initial		Document Number	Issue / Publication Date	Inventor	Filing Date
/A.S./	A1	2003/0087848 A1	05/08/2003	Bratzler et al.	02/02/2001
	A2	5,482,934	01/09/1996	Calatayud et al.	07/20/1994
	A3	5,891,844	04/06/1999	Häfner	06/19/1997
	A4	6,302,331	10/16/2001	Dvorsky et al.	04/20/2000
	A5	6,397,838	06/04/2002	Zimlich Jr. et al.	12/21/1999
	A6	6,454,193	09/24/2002	Busick et al.	04/20/2000
	A7	5,263,475	11/23/1993	Altermatt et al.	03/18/1992
		(corresponds to EP 0505321 A2)			
/A.S./	A8	6,475,467	11/05/2002	Keller et al.	08/02/1999
		(corresponds to WO 00/07567 A1)			
/A.S./	A9	5,733,901	03/31/1998	Gutterer	03/31/1994
		(corresponds to WO 94/22899 A1)			

**OTHER**

Examiner Initial		(Including Author, Title, Date, Pertinent Pages, etc.)
/A.S./	B1	Agertoft, L., "Lower-Leg Growth Rate and HPA Axis Function in Children With Asthma During Treatment With Inhaled Ciclesonide," <i>Journal of Allergy and Clinical Immunology</i> , Vol. 113, No. 2, p. S119 (2004).
	B2	Dent, G., "Ciclesonide," <i>Current Opinion in Investigational Drugs</i> , Vol. 3, No. 1, pp. 78-83 (2002).
	B3	Mealy, N. E., "Ciclesonide," <i>Drugs of the Future</i> , Vol. 26, pp. 1033-1039 (2001).
	B4	Rogers, D. F., "Pulmonary Mucus: Pediatric Perspective," <i>Pediatric Pulmonology</i> , Vol. 36, p. 178-188 (2003).

Examiner /Ali Soroush/	Date Considered 03/28/2009
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.	



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BETHKE et al.

Serial No:  
10/571,311

Filed:  
March 9, 2006

Art Unit:	Unknown
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Examiner:  
Unknown

## FOREIGN PATENT DOCUMENTS

Examiner	/Ali Soroush/	Date Considered	03/28/2009
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.